COOK®

Cook Biotech Incorporated
3055 Kent Avenue
West Lafayette, IN 47906
Phone: 765 497-3355
Toll Free: 888 299-4224
Fax: 765 497-2361
www.cookgroup.com

January 18, 2002

Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane (HFA-305)
Rockville, MD 20852

Petition for Reconsideration: D.C. #K010952

The undersigned submits this petition for reconsideration of the decision of the Commissioner of Food and Drugs in D.C. #K010952.

A. Decision involved

On December 19, 2001, FDA determined that the 510(k) premarket notification for the SURGISIS™ Periodontal Membrane (D.C. #K010952) could not be evaluated for substantial equivalence without clinical data demonstrating efficacy for the indications to be cleared and resorption characteristics of the device.

B. Action requested

The petitioner requests that the Commissioner, or his designee, find the data in the administrative record to be sufficient for determining and for demonstrating substantial equivalence of the SURGISIS™ Periodontal Membrane (D.C. #K010952) to legally marketed predicate devices.

C. Statement of grounds

The history of communications[1] regarding the above named device culminated in a telephone conference between FDA and Company representatives. This conference concluded with agreement that the device could be reviewed for substantial equivalence without clinical data if resorption data were provided and no specific effectiveness claims were sought. The Company agreed with this conclusion because substantial equivalence of function as a membrane may be demonstrated with non-clinical testing, and no new

---

[1] Mar 29, 2001 original 510(k) premarket notification submitted
Jun 25, 2001 FDA request for additional information for review of submission
Jul 24, 2001 additional information submitted with request for telephone conference
Oct 9, 2001 a proposed agenda and background information were provided to FDA
Oct 23, 2001 telephone conference held, 510(k) placed on hold
Oct 29, 2001 telephone conference notes submitted
Nov 19, 2001 additional information characterizing resorption provided to FDA
Dec 19, 2001 510(k) found deficient and withdrawn

02P-0045

PRC 1

questions of safety or effectiveness appeared to be raised. The claims and data were submitted as agreed, but the review was not completed, resulting instead in a stated requirement for clinical data and withdrawal of the premarket notification. The fact that the reviewer who participated in the telephone conference was not available and did not review the additional material may have contributed to the unexpected outcome. It is also worth noting that no comments regarding the telephone conference notes were provided by FDA.

It is our belief that the relevant information in the administrative record was not adequately considered and that the action requested is not frivolous, is sought in good faith, is consistent with sound public policy, and is not outweighed by public health interests.

Thank you for your consideration of this request.

Sincerely,

For Mark Bleyer

Mark Bleyer
President

MB:twh
Enclosures

FedEx Express USA Airbill

FedEx Tracking Number 833174308887

MUR13

Form ID No. 0215

Recipient's Copy

From This portion can be removed for Recipient's records.

Date 1/24/02 FedEx Tracking Number 833174308887

Sender's Name Ted Heise, Mark Bleyer Phone 765 463-7537

Company MED INSTITUTE

Address 1400 CUMBERLAND AVE

Dept/Floor/Suite/Room

City WEST LAFAYETTE State IN ZIP 47906

Your Internal Billing Reference CBI-GUM

To

Recipient's Name Food & Drug Administration Phone 301 827-6869

Company Dockets Management Branch

Address 5630 Fishers Lane (HFA-305)

To "HOLD" at FedEx location, print FedEx address. We cannot deliver to P.O. boxes or P.O. ZIP codes.

Address Room 1061

Dept/Floor/Suite/Room

City Rockville State MD ZIP 20852

4a Express Package Service *Packages up to 150 lbs.*

Delivery commitment may be later in some areas.

XX FedEx Priority Overnight — Next business morning
☐ FedEx Standard Overnight — Next business afternoon
☐ FedEx First Overnight — Earliest next business morning delivery to select locations

☐ FedEx 2Day — Second business day
☐ FedEx Express Saver — Third business day

FedEx Envelope rate not available. Minimum charge: One-pound rate

4b Express Freight Service

Delivery commitment may be later in some areas.

☐ FedEx 1Day Freight* — Next business day
☐ FedEx 2Day Freight — Second business day
☐ FedEx 3Day Freight — Third business day

* Call for Confirmation:

5 Packaging * Declared value limit $500

XX FedEx Envelope*
☐ FedEx Pak* — Includes FedEx Small Pak, FedEx Large Pak, and FedEx Sturdy Pak
☐ Other

6 Special Handling Include FedEx address in Section 3.

☐ **SATURDAY Delivery** — Available only for FedEx Priority Overnight and FedEx 2Day to select ZIP codes
☐ **HOLD Weekday at FedEx Location** — Not available for FedEx First Overnight
☐ **HOLD Saturday at FedEx Location** — Available only for FedEx Priority Overnight and FedEx 2Day to select locations

Does this shipment contain dangerous goods?

One box must be checked.

XX No
☐ Yes — As per attached Shipper's Declaration
☐ Yes — Shipper's Declaration not required
☐ Dry Ice — Dry Ice, 9, UN 1845 ____ x ____ kg

Dangerous Goods (including Dry Ice) cannot be shipped in FedEx packaging.

☐ Cargo Aircraft Only

7 Payment *Bill to:*

Enter FedEx Acct. No. or Credit Card No. below.

☐ Obtain Recip. Acct. No.

XX Sender — Acct. No. in Section 1 will be billed.
☐ Recipient
☐ Third Party
☐ Credit Card
☐ Cash/Check

Total Packages	Total Weight	Total Charges
1		Credit Card Auth.

†Our liability is limited to $100 unless you declare a higher value. See the *FedEx Service Guide* for details.

8 Release Signature *Sign to authorize delivery without obtaining signature.*

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.

Questions? Visit our Web site at fedex.com or call 1.800.Go.FedEx® 800.463.3339.

Rev. Date 10/01•Part #157610G•©1994–2001 FedEx•PRINTED IN U.S.A. GBFE 11/01

8331 7430 8887

0202380645

447